DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

June 28, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Irwin H. Selinger
President and Chief Executive Officer
GF Health Products, Inc.
2935 Northeast Parkway
Atlanta, Georgia 30360

Ref. # - DEN-04-10

Dear Mr. Selinger:

An inspection of your firm, Everest and Jennings LaBac Systems, located at 4965 Kingston Street, Denver, Colorado, was conducted between April 5 - 29, 2004, by FDA Investigator Nathan M. Jornod. This inspection determined that your firm manufactures manual and powered wheelchairs and accessories. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

- Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the established quality policy and objectives and the intent of the Quality System Regulation, as required by 21 CFR 820.20(c).

For example, the only documentation showing management review of your Quality Systems were Certificates of Audit dated 8/21/02 and 2/21/03 . Your procedure, "Management Responsibility," (QPM-B1.B) states that "Management reviews shall occur on

Additionally, your procedure, "Management Review of Quality Systems," (QSP-B101-QA.A) requires that "Management Review shall be held, at Similarly, your "Internal Audits" procedure, (QSP-B201-QA.A) states that internal audits are to be performed ; in accordance with the Internal Audit Matrix. There is no evidence that your firm is conducting management reviews or internal audits according to the above procedures.

- Failure to appoint and document appointment of a management representative, as required by 21 CFR 820.20(b)(3).

Procedure QPM-B1.B, Management Responsibility, requires that your firm appoint a Management Representative who "

Your firm could not provide any documentation showing the appointment of the Management Representative, nor evidence that management reviews or internal audits of the Quality System have been performed according to your procedures.

- Failure to establish procedures for identifying training needs and to ensure that all personnel are adequately trained to perform their assigned responsibilities, as required by 21 CFR 820.25(b).

For example, your "Personnel Training" procedure (QSP-B301-HR.A) states that employees and department managers are to receive training in Current Good Manufacturing Practice and upon completion of this training, it will be documented in each employee file. Your firm's management stated to our investigator that training records are not maintained for your employees as required by your procedures.

- Failure to document corrective and preventive action activities, as required by 21 CFR 820.100(b).

For example, device defects and production quality deficiencies are not captured and documented as required by your "Corrective & Preventive Action Controls" procedure (QSP-J101.B). This procedure states that "A Corrective Action Request...will be issued under the following conditions:

This procedure also requires a Corrective Action Requests Log (CAR Log), Trend Analysis Reports and Trend Analysis Logs be maintained, as well. There is no evidence that quality data is documented as required. In addition, our investigator reviewed Non-Conforming Procedure Reports (NCMR's) and Daily Inspection Logs and found that none contained or provided reference to evaluation for corrective action.

- Failure to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, and to employ appropriate statistical methodology to detect recurring quality problems, as required by 21 CFR 820.100(a)(1).

For example, our inspection revealed that your firm is not trending non-conformances as required by your Corrective and Preventive Action Controls Procedure (QSP-J101.B) or investigating and documenting failures referenced in Returned Material Authorizations (RMA's), NCMR's, or complaints, as required by your Returned Material Controls Procedure (QSP-M502-QA.A) and Failure Analysis Procedure (QSP-J-103-QA.A).

- Failure to submit a written report to FDA of any correction or removal of a device in order to reduce a health risk, as required by 21 CFR 806.10(a)(1).

On [redacted], LeBac Systems issued a letter to customers identifying a "potential safety hazard" with all units containing [redacted] actuators, [redacted]. The letter indicated that failure of the actuators could result in uncontrolled movement of the powered seating system, leading to "possible injury". FDA was not notified of this action.

- Failure to implement procedures that define the responsibility for review and the authority for the disposition of nonconforming product and to document the disposition of nonconforming product, as required by 21 CFR 820.90(b)(1).

Your procedure, Non-Conformance Controls Procedure (QSP-I101-QA.A), states, "Non-conformances shall be investigated and evaluated for determining the cause and any related affects the non-conformance may have on other products or processes. This information shall be recorded on the Non-Conforming Material Report (NCMR), or the Non-Conforming Procedure Report (NCPR) as appropriate." Our investigator reviewed [redacted] NCMR's to determine if non-conformances were investigated and evaluated according to this procedure and found there was no evidence the non-conformances had been investigated and evaluated. Additionally, your Non-Conforming Material Activities procedure (QWI-I10101-QA.A) indicates that NCMR's will be signed and the disposition sections completed by the Material Review Board (MRB), but at least [redacted] NCMR's reviewed by our investigator failed to contain disposition information or review signatures.

- Failure to establish and maintain finished device acceptance activities, as required by 21 CFR 820.80(e).

Review of Device History Records (DHRs) revealed various QA checks required by your procedures were missing or not performed. For example, QA review of in-process testing was not performed; there was no documentation of in-process acceptance testing on the Final Product Inspection Checksheets; QA Final Product Daily Summary Sheets did not contain release authorization signatures; and there were missing or incomplete DHR Contents sheets.

- Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained, as required by 21 CFR 820.72(a).

  Although your firm did provide calibration records for selected pieces of inspection, testing and/or assembly equipment, there was no evidence that your firm has established equipment calibration/maintenance procedures or schedules to ensure your equipment is operating correctly and capable of producing valid results.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act. Continued distribution of violative devices may result in the initiation of regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the correction will be completed. Although we received your letter dated June 3, 2004, in which you outline plans for corrective actions to remedy the deficiencies listed above, your letter does not provide a schedule for these corrective actions, nor does it provide any documentation demonstrating progress toward implementing these corrective actions.

Your reply should be sent to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, CO 80225-0087, Attention: Regina A. Barrell, Compliance Officer. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,

B. Belinda Collins
District Director

cc: Mr. Bruce A. Sanderson
Director of Operations
GF Health Products, Inc.
dba Everest & Jennings LaBac Systems
4965 Kingston Street
Denver, Colorado 80239